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|--------------------------|------------------------|--|---------------------|--|
| Interview Summary | Application No. | | Applicant(s) | |
| | 09/933,638 | | KAZANTSEV ET AL. | |
| | Examiner | | Art Unit | |
| | Anand U. Desai, Ph.D. | | 1656 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Anand U. Desai, Ph.D. (3) _____
 (2) _____ (4) _____

Date of Interview: Week of 10/16/2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
 If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Tried to contact Dr. Lee Crews to discuss a proposed amendment to the claims. Faxed over copy of attached proposed amendment. Examiner called multiple times with no response.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DRAFT PROPOSED NOTICE OF ALLOWANCE - CLAIM AMENDMENT

DETAILED ACTION

1. This office action is in response to the Amendment filed on September 1, 2006. Claims 1-20, 28-30, 34, 35, 39, 44, and 45 have been cancelled. Claims 21-27, 31-33, 36-38, 40-43, and 46 are currently pending and are under examination.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with

*** on ***.

Examiner's amendment to the claims:

21. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8),

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SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii)
separates the first domain from the second domain, wherein the therapeutic agent inhibits an
abnormal or undesirable interaction between the first protein and the second protein and wherein
the first domain and the second domain individually comprise a polypeptide selected from a
group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25
consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid
residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues
including at least one aspartic acid residue or glutamic acid residue, and a polypeptide
comprising 25 consecutive glutamine residues and wherein the first domain and/or the second
domain comprises a polypeptide comprising at least 80% glutamine residues.

22. (Cancelled).

23. (Cancelled).

24. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven
consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven
consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of
alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-
helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of
H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8),
SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii)

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separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues, and wherein the first and second domains are identical.

25. (Cancelled).

27. (Cancelled).

31. (Cancelled).

32. (Cancelled).

33. (Cancelled).

36. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of

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H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii) separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein; wherein the first and/or second protein comprises 7, 10, 15, 20, 25, 30, 35, 36, 37, 38, 39, or 40 consecutive glutamine residues; and wherein the first and/or second protein is Huntingtin, and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues.

37. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii)

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separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein; wherein the first and/or second protein comprises 7, 10, 15, 20, 25, 30, 35, 36, 37, 38, 39, or 40 consecutive glutamine residues; and wherein the first and/or second protein is amyloid-associated protein, and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues.

38. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii) separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein; wherein the

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first and/or second protein comprises 7, 10, 15, 20, 25, 30, 35, 36, 37, 38, 39, or 40 consecutive glutamine residues; and wherein the first and/or second protein is a transcription factor, and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues.

40. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, ~~comprising an alpha-helical region or a beta-sheet~~ and (ii) separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25

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consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues, and wherein the interaction is aggregation.

43. (Currently Amended) A therapeutic agent comprising,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, comprising an alpha-helical region or a beta-sheet and (ii) separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues, and wherein the interaction is dimerization.

46. (Currently Amended) A pharmaceutically acceptable composition comprising a therapeutic agent, wherein the therapeutic agent comprises,

(a) a first domain that bind a first protein, the first protein having at least seven consecutive glutamine residues;

(b) a second domain that bind a second protein, the second protein having at least seven consecutive glutamine residues; and

(c) a third domain that (i) consists of a polypeptide selected from the group consisting of alpha-helical region H1 (SEQ ID NO: 2), the alpha-helical region H2 (SEQ ID NO: 3), the alpha-helical region H3 (SEQ ID NO: 4), the alpha-helical region H4 (SEQ ID NO: 5), a fusion of H1/H2 (SEQ ID NO: 6), a fusion of H2/H3 (SEQ ID NO: 7), a fusion of H3/H4 (SEQ ID NO: 8), SEQ ID NO: 11, and SEQ ID NO: 12, and (ii) separates the first domain from the second domain, wherein the therapeutic agent inhibits an abnormal or undesirable interaction between the first protein and the second protein and wherein the first domain and the second domain individually comprise a polypeptide selected from a group consisting of the first 17 amino acid residues of the Huntingtin protein fused to 25 consecutive glutamine residues, and optionally, a sufficient number of hydrophilic amino acid residues to increase the solubility of the therapeutic agent, the hydrophilic amino acid residues including at least one aspartic acid residue or glutamic acid residue, and a polypeptide comprising 25 consecutive glutamine residues, ~~(e) a third domain that separates the first domain from the second domain, wherein the therapeutic agent inhibits interaction between the first protein and the second protein and wherein the first and/or second protein is Huntingtin; the first and/or second protein is an amyloid-associated protein; or the first and/or second protein is a transcription factor.~~

Conclusion

3. Claims 21, 24, 36-38, 40, 43, and 46 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 20, 2006

DRAFT PROPOSED NOTICE OF ALLOWANCE - CLAIM AMENDMENT